HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
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September 11, 1998

WARNING LETTER NO. 98-NOL-29

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Alvin J. Folse, President/Co-Owner
Louisiana Royal Seafood, Inc.
1031 Frank Wyatt Road
Breaux Bridge, Louisiana 70517-7714

Dear Mr. Folse:

During an inspection of Louisiana Royal Seafood Inc., 1031 Frank Wyatt Road, Breaux Bridge, Louisiana, conducted on August 17-20, 1998, our investigators documented numerous insanitary conditions in your crab meat picking operation. This causes your finished product, picked crab meat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

Objectionable insanitary conditions noted included:

1) Employees walking and standing on ice which was subsequently used to cool cooked crabs;

2) Brown encrusted residues from previous operations inside four trash cans used to hold ice, which was subsequently used to cool cooked crabs;

3) A dead fly in the ice slush, and a piece of crab debris in an opening inside the spare retort used to cool cooked crabs;

4) Rain water leaking from the roof into processing areas in the plant and onto cooked in-process crabs and backed crabs in the storage cooler;

5) On one occasion, an employee handled a live roach, and then handled cooked crabs without washing or sanitizing her hands;

6) Live roaches and crickets in the backing and picking rooms during operations;

7) Employees handling dirty encrusted trash cans and the unsanitized cooler door handle, then contacting cooked crabs without washing or sanitizing their hands;

8) One employee eating a crab claw, then handling cooked crabs without washing or sanitizing his hands;

9) Four of fifteen plastic crates used to hold cooked crabs had scratched, rough surfaces;

10) One crab picker failed to sanitize her knife and cracking block before picking claw crabmeat;

11) Numerous structural defects providing vermin entryways into the plant;

12) Tall grass and weeds outside the plant;

13) Numerous live flies outside the plant, and numerous dead flies in spider webs inside the cook room; and,

14) Numerous other improper employee practices which could lead to contamination of the finished product.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3896, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Additionally, this inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123). The seafood processing regulations, which became effective on December 18, 1997, require you to implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operations to eliminate or minimize the likelihood the identified hazards will occur. These are the kinds of measures prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating

HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA-3501) and the FDA-483 which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

- Failure to provide adequate Critical Limits or monitoring procedures at the backing, picking and packing steps as CCP's for time/temperature control of the significant hazard pathogen growth as required under 21 CFR Part 123.6(b) and 123.6(c)(3). The critical control point begins when a cooked ready-to-eat product is further handled or contacts surfaces that were not heated along with the product. At this point, time above a critical temperature becomes a critical limit and must be monitored, unless it is a very short time, e.g. 30 minutes;

- Failure to provide adequate sanitation monitoring as required in 21 CFR Part 123.11(c), in that sanitation monitoring records do not address control of the safety of the plant's water piping system, prevention of cross contamination, protection of food and food contact surfaces from adulterants, and proper labeling, storage, and use of toxic compounds;

- Failure of the HACCP Plan to include verification procedures as required by 21 CFR Part 123.6(c)(6);

- Failure of the firm to document the calibration of thermometers used to monitor temperatures at CCP's in the HACCP Plan as required under 21 CFR Part 123.8(a)(2)(ii); and,

- The HACCP Plan was not signed and dated as required under 21 CFR Part 123.6(d).

Objectionable equipment and insanitary conditions, as listed on Form FDA-483 and Form FDA-3501, are an indication that sanitation monitoring [21 CFR 123.11(b)] at your firm is inadequate. Calling your attention to the objectionable insanitary conditions is in the interest of having your firm improve its sanitation program consistent with HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. These objectionable insanitary conditions are noted in the body of this letter and on the enclosed FDA-483.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if your response is inadequate, we will assume our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply, relating to these concerns, should be directed to the Food and Drug Administration, Attention: Richard D. Debo, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Mr. Debo at (504) 589-7166 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

Charles H Scarbrough /for

James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483